

**Maryland Board of Pharmacy
Public Board Meeting**

Agenda
Date: June 21, 2017

Name	Title	Present	Absent	Present	Absent
Board Committee					
Ashby, D.	Commissioner				
Bouyoukas, E	Commissioner				
Evans, K.	Commissioner				
Gavgani, M. Z.	Commissioner/President				
Hardesty, J.	Commissioner				
Leikach, N.	Commissioner				
Morgan, K.	Commissioner/Treasurer				
Oliver, B	Commissioner				
Peters, R.	Commissioner				
St. Cyr, II, Z. W.	Commissioner/Secretary				
Toney, R.	Commissioner				
Yankellow, E.	Commissioner				
Board Counsel					
Bethman, L.	Board Counsel				
Felter, B.	Staff Attorney				
Board Staff					
Speights-Napata, D.	Executive Director				
Fields, E.	Deputy Director /Operations				
Brand, E.	Licensing Manager				
Page, A.	Executive Administrative Associate				
Logan, B.	Legislation/Regulations Manager				
Evans, T.	Pharmacist Inspector				

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)										
I. Executive Committee Report(s)	A.) M. Gavgani, Board President B.) Z. St. Cyr, II, Secretary	Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda. 1. Call to Order 2. Sign-in Introduction and of meeting attendees – (Please indicate on sign-in sheet if you are requesting CE Units for attendance) 3. Distribution of Agenda and packet materials 4. Review and approve May 2017 Public Meeting Minutes											
II. A. Executive Director Report	D. Speights-Napata, Executive Director	1. Operations Updates 2. Meetings Update 3. Presentations/Discussion											
B. Operations	E. Fields, Deputy Director/ Operations	1. Management Information Systems (MIS) Unit Updates											
C. Licensing	E. Brand/ Licensing Manager	1. Unit Updates 2. Monthly Statistics <table><tr><td>License Type</td><td>New</td><td>Renewed</td><td>Reinstated</td><td>Total</td></tr><tr><td>Distributor</td><td>62</td><td>508</td><td>0</td><td>1,256</td></tr></table>	License Type	New	Renewed	Reinstated	Total	Distributor	62	508	0	1,256	
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		<table><tr><td>Pharmacy</td><td>16</td><td>0</td><td>0</td><td>2,102</td></tr><tr><td>Pharmacist</td><td>34</td><td>448</td><td>0</td><td>11,349</td></tr><tr><td>Vaccination</td><td>26</td><td>5</td><td>0</td><td>4,423</td></tr><tr><td>Pharmacy Intern - Graduates</td><td>7</td><td>0</td><td>0</td><td>46</td></tr><tr><td>Pharmacy Intern - Students</td><td>75</td><td>24</td><td>0</td><td>947</td></tr><tr><td>Pharmacy Technician</td><td>129</td><td>259</td><td>3</td><td>9,795</td></tr><tr><td>TOTAL</td><td>349</td><td>1,244</td><td>3</td><td>29,918</td></tr></table>	Pharmacy	16	0	0	2,102	Pharmacist	34	448	0	11,349	Vaccination	26	5	0	4,423	Pharmacy Intern - Graduates	7	0	0	46	Pharmacy Intern - Students	75	24	0	947	Pharmacy Technician	129	259	3	9,795	TOTAL	349	1,244	3	29,918	
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D. Compliance	T. Evans/ Pharmacist Inspector	<p>1. Unit Updates</p> <p>2. Monthly Statistics</p> <p>Complaints & Investigations:</p> <p>New Complaints - 39</p> <p>Resolved (Including Carryover) – 40</p> <p>Actions within Goal – 28/40</p> <p>Final disciplinary actions taken – 15</p> <p>Summary Actions Taken – 0</p> <p>Average days to complete - 0</p>																																				

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E. Legislation & Regulations	B. Logan, Legislation and Regulations Manager	<u>1. COMAR 10.34.02.03 D Proof of Proficiency in English</u> <u>2. COMAR 10.34.18 Continual Education</u> <u>3. COMAR 10.34.37 Pharmacy Permit Holder Requirements — Wholesale Distribution and Non-Resident Pharmacy Operations</u> <u>4. COMAR 10.34.05.05 Security Responsibility.</u> <u>5. COMAR 10.34.34.05 Pharmacy Students.</u>	
III. Committee Reports A. Practice Committee	R. Peters, Chair	<u>6. HB0880(Chapter 0525)SB0450(Chapter 525) Open Meetings Act – Annual Reporting Requirement, Web Site Postings, and Training</u> <u>7. a. Contraceptive in Vending Machines</u> <u>7. b. Response by Practice Committee</u> <u>7. c. EC Review</u> <u>8. Prep-Proposal Concept Paper- Nominations for Health Occupation Boards</u> <u>9. Melissa (Lisa) Thompson, Robison & Cole LLP</u> <u>10. Tvine Donabedian Regulatory Affairs Co-op Student, Medisca</u> <u>11. Eswar Abbineni- Telepharmacy</u>	

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B. Licensing Committee	D. Ashby, Chair	<p>1. Review of Pharmacist Applications:</p> <p>a. Applicant #110929 - The Board denied the request to waive the MPJE exam on February 16, 2017. Applicant is again requesting the Board to consider waiving the MPJE re-test as a requirement for reinstatement of her pharmacist licensure. Prior to renewing her license for 2014-2016, she contacted the Board to discuss renewal options. The information she was provided was that Maryland does not offer an “inactive” status for pharmacists who no longer practice in the state of Maryland. However, she was told that she has the option to not renew for the 2014-2016 cycle and re-new at any later time. During this discussion, she says that only two requirements for renewal were stated:</p> <ol style="list-style-type: none"> 1. The fee with a penalty amount added; and 2. Proof of maintained continuing education credits. She says that it was never mentioned that there would be a potential for additional requirements, such as taking the MPJE, if the renewal did not occur within a certain window. <p>This fact pattern is similar to applicant #110499. In both cases, they claim they were not told of the need to take the MPJE if their application expired more than 2 years earlier. Applicant states had she known this she would have never skipped the renewal cycle. As of August 2008, applicant no longer lives or practices pharmacy in the state of Maryland. She has an active license in other states and has always maintained appropriate continuing education requirements during this time. Maryland is the applicant’s primary state and she says it is very important for her to maintain this license in proper order.</p>	

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		<p><u>Licensing Committee's Recommendation:</u> No recommendation</p> <p>b. G. Lee-Thornton - Requesting approval to act as the Maryland licensed pharmacist for two non-resident pharmacies. One pharmacy is a non-dispensing, remote telepharmacy for a hospital. The other pharmacy is a specialty dispensing pharmacy. There is a proposed regulation that prohibits a Maryland licensed pharmacist from being employed by more than one non-resident pharmacy.</p> <p><u>Licensing Committee's Recommendation:</u> No recommendation</p> <p>c. M. Monique - Applicant is requesting to use her current work experience as the Director, US Medical Affairs, Hematology, towards the 1,000 hours of pharmacy service required for licensure. She states that she has worked in the pharmaceutical industry in several different capacities and that all of her roles have allowed her to continue to utilize the skills and knowledge she acquired as a clinical pharmacist.</p> <p>Her duties and responsibilities include the following,</p> <ul style="list-style-type: none"> • Lead the development, communication, and implementation of US medical affairs strategy for assigned therapeutic area(s)/product(s) - Hemophilia A/B with Inhibitors and Acquired Hemophilia A. • Collaborate with internal stakeholders to provide scientific input, strategic support, and education/training. • Ensure timely development, implementation, maintenance, and medical review of clinical, 	

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		<p>scientific, and HEOR slide presentations and other resources for use by field medical teams (medical science liaisons [MSLs] and medical and scientific outcomes liaisons [MSOLs]).</p> <ul style="list-style-type: none"> • Coordinate and conduct training for field medical teams and sales force teams. • Develop and maintain relationships/partnerships with key opinion leaders (KOLs) and other external stakeholders (i.e., payers), medical/professional organizations, and patient advocacy groups in regards to scientific exchange, research, medical education, and other medical affairs initiatives. • Conduct country analyses to identify research and education gaps. • Design and/or review and approve regional post-approval studies. • Identify research grants that advance the science and knowledge of the biologic basis of inhibitors in Hemophilia A and acquired Hemophilia A. • Participate in independent medical education (IME) grants review board as voting member. • Collaborate with Global Medical Affairs, R&D, and Clinical Research Organizations (CRO) for study site recruitment and support other research-related activities for post-authorization studies. • Provide input into product life-cycle planning. 	

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		<ul style="list-style-type: none"> • Lead product launch activities on behalf of US Medical Affairs team/support marketing and sales organization on product launch activities. • Develop budget and provide ongoing planning, reporting and monitoring of executed tactics. • Lead the coordination and execution of advisory board meetings to understand data/scientific/educational gaps. • Provide scientific support in the development of publications. • Participate in select global and regional congresses, symposia, and medical committees. <p><u>Licensing Committee's Recommendation:</u> Deny</p> <p>d. S. Adesina - Pharmacist is requesting a refund of his license renewal fee that was paid before the expiration date. The license expired prior to the completion of the renewal application. Applicant states he was advised that, because his completed application for renewal was not received before the deadline, he had to apply for reinstatement.</p> <p><u>Licensing Committee's Recommendation:</u> Approve</p> <p>e. Applicant #110499 - Applicant is requesting to have the MPJE exam waived and the fees for reinstatement application refunded under the advisement of the Board not to renew her pharmacist licensure in 2015. The timing of her application suggests that she waited until right after the expiration of her license to seek reinstatement. She claims that no one told her that if she sought</p>	

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		<p>reinstatement she would have to take another exam. Similar fact pattern as Applicant #110929. <u>Licensing Committee's Recommendation:</u> No recommendation</p> <p>2. Review of Pharmacy Intern Applications: NONE</p> <p>3. Review of Pharmacy Technician Applications: NONE</p> <p>4. Review of Distributor Applications: NONE</p> <p>5. Review of Pharmacy Applications: NONE</p> <p>6. Review of Pharmacy Technicians Training Programs:</p> <p>a. Giant Eagle Technician Training Program - This program and examination were originally approved in 2009. The company recently submitted an updated program description. The Board voted to not approve the program on May 17, 2017. The company submitted additional documentation and a request for approval of its program and examination. <u>Licensing Committee's Recommendation:</u> Approve</p> <p>7. New Business:</p> <p>a. Technician Application Edit - Disciplinary Committee wants to add "job title" in the Employment Information section for all technician applications. <u>Licensing Committee's Recommendation:</u> Approve</p> <p>b. INO Therapeutics - Company is requesting an extension of the renewal period pending the receipt of</p>	
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		<p>background check results. Application was received May 24, 2017. <u>Licensing Committee's Recommendation:</u> No recommendation</p> <p>c. Merchant Gases/Airgas - Company is requesting an extension of the renewal period pending the receipt of background check results. Application was received May 24, 2017. <u>Licensing Committee's Recommendation:</u> No recommendation</p> <p>d. Smiths Medical - Company is requesting an extension of the renewal period pending the receipt of background check results. Application was received May 24, 2017. <u>Licensing Committee's Recommendation:</u> No Recommendation</p>	
C. Public Relations Committee	E. Yankellow, Chair	Public Relations Committee Update:	
D. Disciplinary	K. Morgan, Chair	Disciplinary Committee Update	
E. Emergency Preparedness Task Force		Emergency Preparedness Task Force Update	
IV. Other Business & FYI	M. Gavgani, President		
V. Adjournment	M. Gavgani, President	<p>A. The Public Meeting will be adjourned.</p> <p>B. M. Gavgani will convene a Closed Public Session to conduct a medical review committee evaluation of confidential applications.</p>	

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		<p>C. The Closed Public Session will adjourn. Immediately thereafter, M. Gaygani will convene an Administrative Session for purposes of discussing confidential disciplinary cases.</p> <p>D. With the exception of cases requiring recusals, the Board members present at the Public Meeting will continue to participate in the Closed Public Session and the Administrative Session.</p>	